Senior Global Program Regulatory Manager

Job ID
REQ-10010321
Jul 09, 2024
United Kingdom

Summary

1,800+ associates. 86 countries. One Regulatory Affairs. At Novartis your voice, experience, and quality mindset can truly make a difference in Regulatory Affairs (RA). Novartis has a unique and promising portfolio with 70 projects as potential NMEs in development, 65 projects in Phase 3 or already undergoing registration, and 100 Phase 1/2 projects. We also focus on rare disease areas; in fact, more than 80% of our innovation is targeted on areas of high unmet need. In many cases, we can offer family friendly work flexibility to facilitate your physical and mental health. Read on to learn about the role available in Regulatory Affairs. We hope you will consider joining our global OneRA family.

About the Role

The Sr GPRM works under limited supervision of the regulatory affairs (RA) program lead to develop and implement the global regulatory strategy for program(s) through development, registration and post approval in the assigned region(s). They may act as the RA program lead on programs of limited complexity. The Sr GPRM is a member of the RA sub team and may lead or represent RA in regional or cross-functional teams. They may also act as a subject matter expert and/or assume mentoring role.

Major accountabilities:

Regulatory Strategy
• Provides input to global program regulatory strategy, including regulatory designations & innovative approaches
• May provide global RA leadership for specific part of the program or act as RA program lead for program of limited complexity
• Represents RA or leads in regional RA or cross-functional activities
• Determines requirements and coordinates activities for Health Authority (HA) interactions. May lead HAs meetings together with RA program lead.
• May serve as local HA liaison (e.g., FDA or EMA).

Regulatory Submissions
• Leads planning, preparation and submission of clinical trials.
• Coordinates, plans, and prepares for submission of initial registration and post-approval applications, including authoring of Module 1 documents

Regulatory Excellence and Compliance
• Ensures timely RA input and submission of regulatory compliance and maintenance reports (e.g. aggregate safety reports, annual reports, renewals, etc) across assigned regions

Education
Bachelors degree preferred (Minimum/desirable)
• Science based BS or MS. Advanced degree (e.g., MD, PhD, PharmD, regulatory) preferred
• Advanced understanding of pharmaceutical development, clinical trials, analysis and interpretation of scientific data
• Awareness of post-marketing/brand optimization strategies and commercial aspects.
• ≥4 years involvement in regulatory and pharmaceutical development spanning activities in Phases I-IV in 1 or more major region.
• Experience in leading cross-functional teams
• Strong collaboration, communication influencing and problem solving skills.
• Organizational awareness (e.g., interrelationship of departments, business priorities)

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? https://www.novartis.com/about/strategy/people-and-culture

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

Division
Development
Business Unit
Innovative Medicines
Location
United Kingdom
Site
London (The Westworks)
Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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